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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

March 29, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02-29

Brian M. Packard
President and CEO
Minnesota Extrusion, Inc.
11760 Justen Circle, Unit B
Maple Grove, MN 55369

Dear Mr. Packard:

During an inspection of your establishment located in Maple Grove, Minnesota on January 23, 24, 29 & 30, 2002, our investigator determined that your establishment manufactures balloon catheters and other products which are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820).

Quality system deficiencies were observed in the areas of management responsibility, quality audits, corrective and preventive action, and process validation. Deficiencies include, but are not limited to:

1. Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example, management did not ensure that procedures for management reviews, quality audits and corrective and preventive actions were fully implemented.

2. A quality plan was not established [21 CFR 820.20(d)].

3. Management reviews were not conducted at defined intervals [21 CFR 820.20(c)]. For example, Standard Operating Procedure (SOP) No. 049 requires an annual management review meeting, but the last documented management review was done on 10/5/99.

4. Quality audits were not conducted as prescribed by internal procedures to verify that the quality system is effective in fulfilling the firm's quality system objectives [21 CFR 820.22]. For example, SOP No. 22 required a annual quality system audit, but no internal audits have been done since 1999.

5. The corrective and preventive action procedures addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems were not implemented [21 CFR 820.100(a)(1)].

6. The manufacturing process for the measuring balloon catheter has not been validated and approved according to established procedures [21 CFR 820.75(a)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

We have received your letter dated March 8, 2002, which replied to the FDA 483 issued on January 30, 2002. The corrective actions that you have planned appear to be adequate. We will conduct a follow-up inspection in the near future to verify the implementation and effectiveness of the corrections.

Please update this office in writing within 15 working days of receipt of this letter of the status of the actions taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Compliance Officer Timothy G. Philips at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/rfk